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ORIGINAL ARTICLE

Brief hypnotherapeutic–behavioral intervention for functional abdominal pain and irritable bowel syndrome in childhood: a randomized controlled trial

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Abstract Functional abdominal pain and irritable bowel syndrome are two prevalent disorders in childhood which are associated with recurrent or chronic abdominal pain, disabilities in daily functioning, and reduced quality of life. This study aimed to evaluate a brief hypnotherapeutic-behavioral intervention program in a prospective randomized controlled design. Thirty-eight children, 6 to 12 years of age, and their parents were randomly assigned to a standardized hypnotherapeutic–behavioral treatment (n=20) or to a waiting list condition (n=18). Both groups were reassessed 3 months after beginning. Primary outcome variables were child-completed pain measures and pain-related disability. Secondary outcome variables were parent-completed measures of their children's pain and pain-related disability. Health-related quality of life from both perspectives also served as a secondary outcome. In the treatment group, 11 of 20 children (55.0 %) showed clinical remission (>80 % improvement), whereas only one child (5.6 %) in the waiting list condition was classified as responder. Children in the treatment group reported a significantly greater reduction of pain scores and pain-related disability than children of the waiting list condition. Parental ratings also showed a greater reduction of children's abdominal pain and pain-related disability. Health-related quality of life did not increase significantly. *Conclusions*: Hypnotherapeutic and behavioral interventions are effective in treating children with long-standing AP. Treatment success of this brief program should be further evaluated against active interventions with a longer follow-up.

Keywords Functional abdominal pain · Irritable bowel syndrome · Children · Hypnotherapy · Randomized–controlled trial

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Introduction

Recurrent or chronic abdominal pain (AP) is the most prevalent pain syndrome in childhood [15, 42, 45]. Because of the predominant absence of organic diseases [1, 54], the recurring occurrence of AP is mostly classified as a functional gastrointestinal disorder (FGID) [39]. Functional abdominal pain (FAP) and irritable bowel syndrome (IBS) are the most frequent FGIDs in childhood [10, 23] and are characterized by recurrent or continuous AP for at least 2 months [39]. IBS is additionally accompanied by changes in defecation (diarrhea and/or constipation) and/or relief of symptoms after defecation [39]. In the past, many studies did not use coherent criteria and did not distinguish between different symptom patterns such as FAP or IBS. This contributed to inconsistent prevalence rates in the range between 1 and 19 % [7].

A considerable portion of visits in doctors' offices is caused by cases of AP of undetermined origin [29, 44]. Frequent AP is associated with substantial disabilities in quality of life and daily functioning [59], particularly in attending school [29, 38]. A part of children with AP is at risk of symptom persistence till adulthood [5, 21, 24, 53]. Children with AP are found to score higher in questionnaires assessing psychopathological symptoms especially internalizing disturbances such as anxiety and other somatic

complaints [14, 17, 52]. They also feature a high rate of psychiatric disorders such as anxiety disorders and depression [4, 36]. Beyond psychological symptoms, a few studies report abnormalities in the function of the gut in terms of a heightened sensitivity of the gut [12] and modified gut motility [46].

Whereas dietary and pharmacological interventions are lacking in high quality evidence [26, 28], cognitive–behavioral interventions seem to be effective [27, 35]. Derived from good evidence in treating adults with long-standing IBS with hypnotherapy (HT) [16, 18, 58], this might also be a promising approach in handling FAP and IBS in childhood [47–49]. The most comprehensive study in HT treatment of FAP and IBS in children and adolescents (8–18 years) by a Dutch workgroup [48, 49] could demonstrate that HT was highly superior to standard medical care, even in a long-term follow-up. A study in the United States was able to show that self-administered audio-recorded HT for children and adolescents with FAP (6–15 years) was superior to a waiting list condition [47]. The employment of standardized psychotherapeutic interventions in childhood FGIDs is not common in Germany [20, 44]. Therefore, we conducted a brief intervention program based on hypnotherapeutic and behavioral methods. With this concept, we focused on children aged 6 to 12. Preliminary results showed encouraging effects regarding pain characteristics and daily functioning [22]. The current study aimed on evaluating this intervention program in a prospective randomized controlled design, comparing a treatment group (TG) with a wait-list control group (WCG) three months after beginning.

Materials and methods

Study participants

Children had to be between 6 and 12 years of age. Inclusion criteria for the study were based on the Rome III definition of FAP and IBS. For participation, children had to feature recurrent or continuous AP for at least 2 months occurring at least once a week. In case of IBS, AP had to be associated additionally with two or more of the following at least 25 % of the time: (1) improved with defecation, (2) onset associated with a change in frequency of stool, (3) onset associated with a change in form (appearance) of stool. A confirmation about the absence of organic diseases had been collected from the attending pediatrician or gastroenterologist. Exclusion criteria for the study were (1) ongoing specific treatment by another health care specialist (physician or psychotherapist) and (2) fulfilled criteria for functional dyspepsia or abdominal migraine.

Participant families were recruited from public announcements in local newspapers and at pediatricians' offices. The intervention was conducted at a university psychotherapeutic outpatient clinic. Fifty-four interested families were screened for eligibility, and 38 families (70.4 %) finally entered the trial. Reasons for exclusion of participants were nonfulfillment of diagnostic criteria (n=8) and refusal of participation (n=7). One family was excluded due to very bad German language skills. Remaining 38 participant families were randomly assigned following simple randomization procedures (computerized random number generator) to TG (n=20) or WCG (n=18). Details on recruiting are illustrated in Fig. 1.

All families gave informed consent to participate in the study. The study had been approved by the ethics committee of the University Hospital Tübingen.

Treatment

The treatment program [22, 43] consisted of four group sessions which split up in two children sessions and two parent sessions in a weekly sequence. Group size was between four and seven families. The treatment program was strictly standardized by a manual, and participants also received written information. Each treatment session lasted 90 min and was conducted by trained psychologists. The two sessions for the children addressed their abilities for self-instruction, relaxation, imagination, and provided information about the link between stress and AP. Both sessions included standardized hypnotherapeutic trances which aimed at increased well-being, the ability of being brave, and the ability of managing the pain (closing the “pain gate”). Children were instructed to practice these trances, recorded on a CD, at home for 4 weeks at least five times a week (each 15–20 min). The two sessions for the parents comprised of information about FGIDs and their link to anxiety and stress, the individual identification of triggers, and information about positive educational strategies respective operant learning mechanisms in terms of secondary gain.

Measures

Children and their parents in the TG filled out questionnaires before the start of the treatment. The treatment lasted for 4 weeks. Two months after ending the treatment (3 months after the start), the participants were reassessed. Participant families in the WCG filled out questionnaires before the start of the waiting time and 3 months after the start of the waiting time.

Baseline measures

The Child Behavior Checklist 4/18 (CBCL) [6] consists of 113 behavior and emotional problems during the previous 6 months which were rated by the parents as being not true, sometimes or somewhat true, or very or often true. The

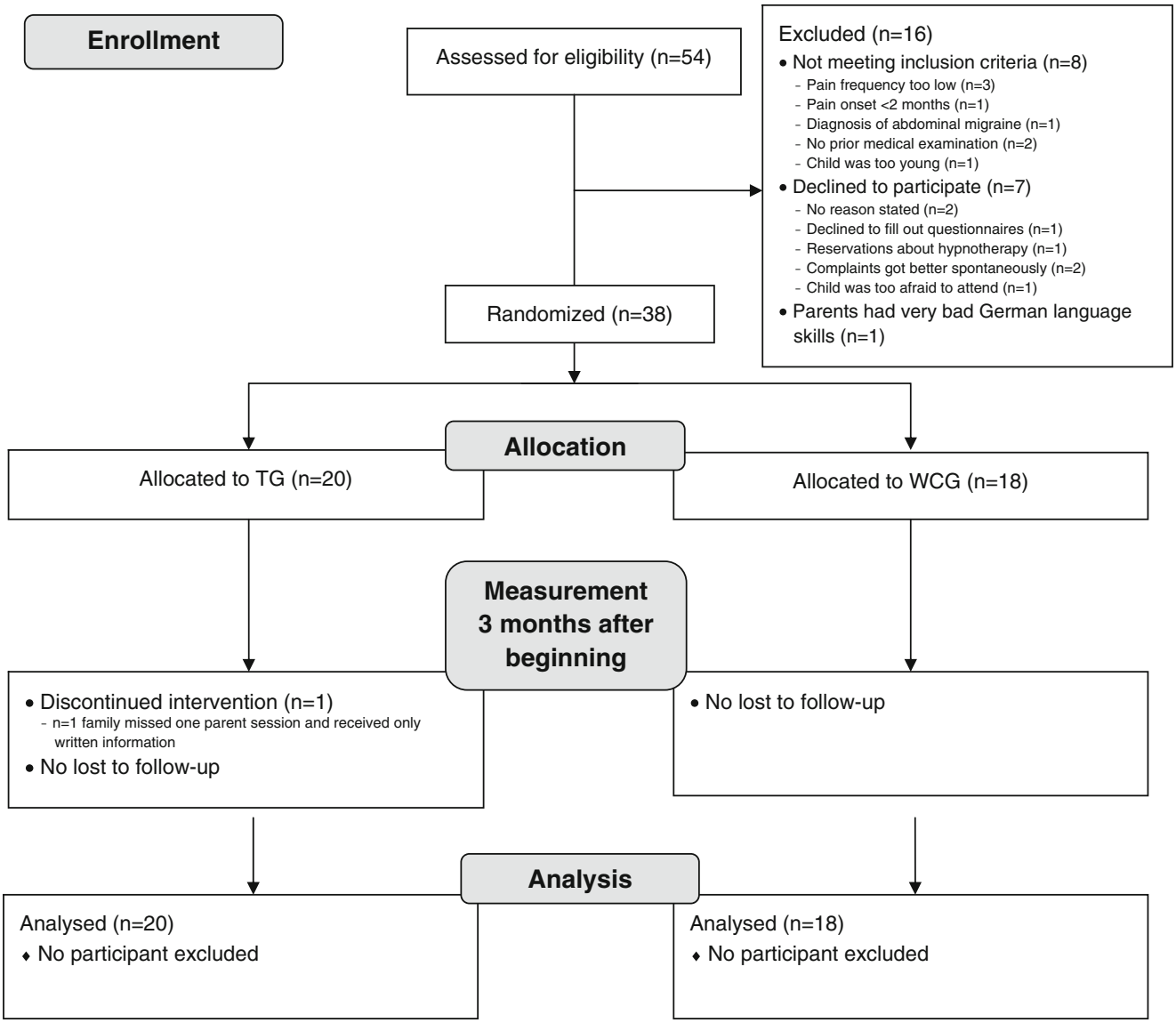

Fig. 1 Flow diagram of study participants

CBCL is a widely used and well validated screening instrument for children's psychopathology [32]. We employed the three major scores of internalizing difficulties, externalizing difficulties, and total difficulties. The CBCL was only used for baseline comparisons of children's psychopathology and was therefore not included in the follow-up measurement.

Primary outcome measures

Because of the risk of possible underreporting, measurement of pain should be obtained directly from the children and serve as primary outcome variable [2]. Participating children kept a pain diary for 2 weeks at both measurement points. The pain diary recorded the number of days with AP, the mean intensity, and the mean duration of pain episodes. It was also assessed whether the child missed school because of AP. Pain intensity was rated on a numeric rating scale from 1 to 10 ("very little pain" to "the most pain possible"). The duration of AP was scored as: 0 = no pain, 1 = a few minutes, 2 = about half an hour, 3 = about an hour, 4 = between 1 and 2 h, 5 = 3 or 4 h, 7 = most of the day and 8 = all day (it never completely stops). The classification of pain duration was taken over from the widely used abdominal pain index (API) [55].

The Rome expert panel recommended that in trials for FGIDs, one primary outcome measure should be the percentage of subjects meeting a predetermined clinical outcome [30]. For this purpose, we calculated an additive index of AP based on the three pain ratings of the pain diary (days with pain + pain duration + pain intensity). Because of the different scaling of the three pain ratings, the index of AP is calculated from standardized z values. This procedure considers various symptom patterns (e.g., scarce but

intensive AP or frequent but weak AP) and is similar to the API [55]. In many studies, a 50 % symptom improvement is considered to be a reasonable definition of a treatment responder [8], but we applied a more conservative categorization, which was also used in a previous trial addressing childhood FGIDs [48, 49]. Participating children with >80 % improvement of the index were considered as responders with a clinical remission. An improvement between 30–80 % was defined as "significant improvement." The treatment was considered to be unsuccessful if the scores improved only <30 % or got worse.

The self-reported pain-related disability was assessed by the one-dimensional pediatric-pain disability index (P-PDI) [25]. The P-PDI assesses pain-related impairment in 12 daily activities, with each ranging from 1 = never to 5 = always. The self-report featured good internal consistency (α=.87) [25]. In our sample, we found an internal consistency of α=.85.

Secondary outcome measures

Parents were asked to rate their children's AP with the parental form of the five-item abdominal pain index (API) [55]. The API assessed the frequency of AP within the last 2 weeks on a 6-point scale from "not at all" to "every day." The daily frequency was also rated on a 6-point scale from "none" to "constant during the day." Usual duration of a pain episode was rated on a 9-point scale from "none" to "all day." The usual intensity of a pain episode and the maximum intensity were scored using two 10-point scales ranging from "no pain" to "the most pain possible." Because of the different answer formats of the five pain ratings, the variables were *z*-standardized and added up to provide a balanced index of AP. Previous studies [55] have shown adequate internal consistency of the API (α =.80–93), which could be confirmed in our sample (α=.87).

As a secondary outcome, the P-PDI was also administered to the parents. The parent-completed P-PDI is parallel to the previously described children version. In our sample, the internal consistency of the parental report was α=.84.

Health-related quality of life (HRQoL) is recommended as secondary outcome in trials for the treatment of FGIDs [30]. It was assessed in children using the revised German KINDL questionnaire [40], which exhibits three age versions. The KINDL is a well validated measure of HRQoL [40, 41]. We applied the KINDL-Kiddy (age 4–7 years) and the KINDL-Kid (8–12 years) with both parental and self-appraisals. The KINDL-Kid consists of 24 items and the KINDL-Kiddy of 22 items, each ranging from 1 = never to 5 = always. The total score ranges from 0 (lowest HRQoL) to 100 (highest HRQoL).

Statistics

Baseline differences between the two groups were examined using χ^2 tests for frequencies and *t* tests for data based on means. When normal distribution could not be assumed, Mann–Whitney U test was used for comparisons between means. Mann–Whitney U test was also used for comparing ordinal scaled data. Changes from pre to post were calculated with univariate repeated-measures ANOVAs. Dependent variables yielding univariate significance were included in two repeated-measures MANOVAs (one for children's and one for parent's perspective) to control for interactions among the dependent variables and multiple testing. In case of superiority of one treatment group, we expected significant time × group interactions in (M)ANOVAs. (M)ANOVA effect sizes are reported as η^2 (small effect η^2=0.01, medium effect η^2=0.06, strong effect η^2=0.14). All tests were two-tailed, and the significance level was set at p<0.05. Based on our previous results [22], we expected medium effect sizes regarding the time × group interactions. To ensure medium effects with a power of .80, at least 34 children (17 per group) had to be included in the trial. Statistical analyses were performed using SPSS (version 20).

Results

A total of 38 children and their parents entered the trial. The sample consisted of 24 girls (63.2 %) and 14 boys (36.8 %) with a mean age of M=9.37 years (SD=1.72). An amount of 29 children, 76.3 % of the sample, fulfilled criteria for FAP, and 9 children were diagnosed to have IBS (23.7 %). On average, the onset of complaints was 34.6 months ago (SD=40.41; 2.9 years).

As reported in Table 1, there were no differences between the TG and WCG after randomization. TG and WCG did not differ with regard to demographic characteristics, pain characteristics, or behavioral and emotional problems (CBCL).

Primary outcomes

Children in the TG reported a greater reduction of days with AP compared to children in the WCG, which is supported by a significant time × group interaction (F=4.25, p=.046, η^2=.106). At follow-up, children in the TG reported 1.8 pain days during the diary period of 2 weeks (decrease of 6.1 days) whereas children in the WCG reported 6.2 days (decrease of 3.3 days). Children's reports of mean intensity of pain episodes decreased significantly stronger in the TG than in the WCG group (F=8.27, p=.007, η^2=.187) from 4.2 points to 1.6 points, respectively, 5.0 points to 4.5 points (scaled from 1 to 10). Mean duration of pain episodes also shortened significantly more in the TG group (F=6.57, p=.015, η^2=.154). As missing school was reported seldom at baseline and at follow-up, no sound calculation could be carried out. Pain-related disability as reported

Table 1 Baseline characteristics of participants by treatment group

	TG n=20	WCG n=18	t / χ^2 / U	p
Mean age (SD)	9.11 (1.65)	9.66 (1.79)	t=−.989	p=.329
Gender (female to male)	11 to 9 (55.0 to 45.0 %)	13 to 5 (72.2 to 27.8 %)	χ^2=1.21	p=.272
Duration of AP in months (SD)	30.45 (41.04)	39.22 (40.36)	t=−.663	p=.511
Consultations of a physician in the last 3 months (SD)	1.06 (0.90)	1.97 (2.02)	U=121.50	p=.303
Diagnosis according to Rome III				
FAP (%)	14 of 20 (70.0 %)	15 of 18 (83.3 %)	χ^2=.932	p=.334
IBS (%)	6 of 20 (30.0 %)	3 of 18 (16.7 %)		
Missed school days in the last 3 months				
Never	10 of 20 (50.0 %)	7 of 18 (38.9 %)	U=143.00	p=.290
1 day	6 of 20 (30.0 %)	4 of 18 (22.2 %)		
2 to 7 days	4 of 20 (20.0 %)	5 of 18 (27.8 %)		
More than a week	0 of 20 (0 %)	2 of 18 (11.1 %)		
Pain characteristics (parental rating)				
Common intensity of pain episodes in the last 3 months [1–10] (SD)	4.08 (1.34)	4.18 (1.35)	t=−.229	p=.820
Maximum intensity of pain episodes in the last 3 months [1–10] (SD]	5.60 (1.82)	4.88 (1.73)	t=1.22	p=.229
Common duration of pain episodes in the last 3 months [score 1–8] (SD)	3.45 (2.28)	3.39 (2.17)	U=176.50	p=.919
API score of the last 2 weeks, z values (SD)	1.56 (2.90)	1.85 (2.98)	t=−.305	p=.762
Pain characteristics (child's rating)				
Number of recorded days with pain in diary [0–14] (SD)	7.90 (4.82)	9.50 (4.08)	t=−1.10	p=.280
Mean intensity of pain episodes in diary [1–10] (SD)	4.18 (1.19)	5.03 (1.65)	t=−1.83	p=.075
Mean duration score of pain episodes in diary [1–8] (SD)	3.40 (2.35)	3.50 (2.36)	t=−.131	p=.897
Emotional/behavioral problems (parental rating)				
CBCL internalizing T-score (SD)	67.00 (7.70)	67.28 (7.86)	t=−.110	p=.913
CBCL externalizing T-score (SD)	55.75 (7.49)	56.50 (6.96)	t=−.319	p=.752
CBCL total T-score (SD)	62.50 (7.83)	62.61 (7.80)	t=−.044	p=.965

M mean, *SD* standard deviation, *TG* therapy group, *WCG* waitlist–control group, *AP* abdominal pain, *FAP* functional abdominal pain, *IBS* irritable bowel syndrome, *API* abdominal pain index, *CBCL* Child Behavior Checklist 4/18

by the children improved from baseline to post-measurement in the TG; whereas, it remained stable in the WCG (F=6.73, p=.014, η^2=.161).

The responder analysis was based on an additive index of AP derived from the children's pain diaries. In the TG 11 of 20 children (55.0 %) showed clinical remission (>80 % improvement), whereas only one child (5.6 %) in the WCG was classified as responder (p=.002). Five children (25.0 %) in the TG and five children in the WCG (27.8 %) showed a significant symptom improvement between 30–80 %. Four children of the TG (20.0 %) and 12 children (66.7 %) of the WCG did not improve or got worse.

Secondary outcomes

Parent's reports of AP symptoms were measured using the API. From baseline to follow-up, univariate analysis revealed a significantly stronger reduction of symptoms in the TG (F=7.57, p=.009, η^2=.174). Pain-related disability as reported by the parents also improved significantly more in the TG (F=7.27, p=.011, η^2=.168).

Self-reported HRQoL improved in the TG and not in the WCG at follow-up, but the interaction between group and time factor failed to reach significance (F=2.56, p=.120). Parental rating of HRQoL improved in both conditions and showed no differential effect between the two groups (F=0.18, p=.678).

Multivariate analysis for child-completed and parent-completed measures

An additional repeated-measures MANOVA which included the three child-completed pain parameters and the pain-related disability demonstrated that all four parameters still reached significance regarding the time × group interaction, indicating a superiority of the TG from the children's perspective. Detailed values can be obtained from Table 2.

A second multivariate analysis for the parent's perspective included also the variables which were found to be significant in univariate analysis. As shown in Table 2, both AP symptoms und pain-related disability still reached significance regarding the time × group interaction in the MANOVA, indicating a superiority of TG from the parent's perspective in terms of AP symptoms and disability.

Discussion

The primary result of this study is that a brief hypnotherapeutic and behavioral intervention (TG) was able to reduce the pain frequency, pain duration, and pain intensity significantly compared to a waiting list control group. The superiority of the TG could be ascertained for children's and parent's reports of the symptoms. Additionally, we could demonstrate that children receiving the treatment showed a significant stronger improvement of pain-related disability compared the children who were waiting on the treatment to start. Interestingly, the TG showed no superiority regarding HRQoL from children's or parent's perspective. At follow-up, the TG featured a high rate of treatment responders (55 %), whereas only one child of the WCG improved to this extent. This result corresponds to the finding by Vlieger and colleagues [48], who found a rate of 59 % treatment response (>80 % improvement) after 3 months in a group of children and adolescents with FAP or IBS receiving HT. Van Tilburg and colleagues reported in their HT trial a treatment response rate (≥50 % improvement) of 63 % after 1 month and 63 % after six months. On the one hand, the high rate of treatment responders is remarkable since the majority of children suffered from long-standing AP. On the other hand, this is in line with previous research in adults, which has shown that HT is highly effective in the treatment of adult patients with severe IBS, who did not benefit from other treatments [18].

Even though most children with frequent AP are lacking explanatory organic diseases [1] and a substantial proportion of children exhibits psychological problems [14, 17, 52], it cannot be concluded that frequent nonorganic AP is caused by psychological factors [11]. FGIDs are thought to be strongly linked to a disordered brain–gut interaction [13]: Stress and unpleasant emotional states lead to hypervigilance and hence to an increase of arousal of the autonomous nervous system and the endocrine system, which may contribute to a heightened sensitivity of the gut and modified gut motility [13, 31]. Additionally, persistent experiences of pain may have an adverse effect on psychological symptoms. The efficiency of psychotherapeutic treatments [27] is probably caused by their modification of this interplay of psychological and physiologic processes (e.g., reduction of arousal and change of coping behavior).

HT aims to induce a hypnotic state (“trance”), which can be achieved by deep relaxation or imagination and is followed by direct and indirect suggestions. It is assumed that persons in this state have a better ability to assimilate new concepts about their problem [19], but the mechanisms by which HT has an influence on FGIDs are not well known. Till now, there is evidence (mainly from adults' studies) that HT reduces autonomic reactivity [34], influences gut motility [57], and normalizes visceral sensitivity [33]. In contrast, the only intervention study which examined a sample of children and adolescents with FAP or IBS by physiological measures concluded that the symptom reduction following HT could not be explained by relief of visceral (rectal) sensitivity [50].

The behavioral elements of our intervention addressed the parents' direct behavioral response on their children's somatic complaints and the explanation of a biopsychosocial model. Based on operant conditioning, parental reaction has a notable influence on childhood AP [51, 56]. Therefore, parents might contribute to a maladaptive role by showing positive consequences to it. Other studies highlight the importance of parental acceptance of a biopsychosocial model for the explanation of the child's symptoms which was associated with long-term symptom recovery [9, 37]. A three-session cognitive–behavioral intervention study by Levy and coauthors [35] aimed mainly at modifying the families' response on illness behavior of the child and could demonstrate a long-lasting reduction of parent-reported AP in a large sample. Beyond this, the empowerment of parents to take an active role in their child's treatment might help to reduce helplessness and contribute crucially to treatment success. However, it must be pointed out that our combination of HT and behavioral interventions did not allow drawing conclusions of which components were effective and which were not.

We did not find an effect regarding HRQoL. This may be due to the already high HRQoL values at baseline. Both groups exhibited baseline values between 69 and 70 points from both perspectives which is only one standard deviation or less below the means of population [3]. As reported by the children, only the TG improved between the two time points but failed to reach significance. Parents in both conditions reported a similar increase of HRQoL (6.6 or 8.4 points). A condition-specific measure for assessing HRQoL might be more suitable.

The treatment gained a high compliance. No family dropped out during the intervention, and all families completed their follow-up measures. Previous results showed a high acceptance of the treatment program [22]. No adverse side effects were mentioned or observed.

Table 2 Means and multivariate comparison of primary outcome measures for treatment group and wait-list control group

	Group	Pre	Post	Time × group interaction		
		M (SD)	M (SD)	F	p	η^2
Child's rating						
Number of recorded days with pain in diary [0–14]	TG	7.90 (4.82)	1.80 (2.95)	4.83	.035	.121
	WCG	9.50 (4.08)	6.17 (4.55)			
Mean intensity of pain episodes [1–10]	TG	4.18 (1.19)	1.60 (2.45)	8.80	.005	.201
	WCG	5.03 (1.65)	4.46 (2.33)			
Mean duration score of pain episodes [1–8]	TG	3.40 (2.35)	1.20 (1.47)	6.64	.014	.159
	WCG	3.50 (2.36)	3.50 (2.53)			
Pain-related disability score (P-PDI) [12–60]	TG	28.24 (8.10)	18.53 (9.44)	6.73	.014	.161
	WCG	28.17 (10.51)	27.67 (7.07)			
Parental rating						
API score of the last 2 weeks, *z* values	TG	1.56 (2.90)	−3.91 (3.56)	7.57	.009	.174
	WCG	1.85 (2.98)	0.63 (4.57)			
Pain-related disability score (P-PDI) [12–60]	TG	25.01 (6.62)	16.13 (5.23)	7.27	.011	.168
	WCG	24.89 (8.09)	22.44 (6.33)			

M mean, *SD* standard deviation, *TG* therapy group, *WCG* waitlist–control group, *P-PDI* pediatric pain disability index, *HRQoL* health-related quality of life, *API* abdominal pain index

A great strength of our concept is that the treatment is very short, and that it is administered in small groups. This makes it easy and cheap to implement. Although children with AP are affected by this condition from months to years [53], there is growing evidence of the efficiency of very brief psychosocial interventions in treating AP [35, 47, 48].

This study delivers preliminary evidence that our standardized treatment is effective among children with long-standing FAP or IBS, but there are also several limitations: First, the control group was a wait-list control group and did not receive an active treatment. The use of the wait-list control group provides only evidence that the outcome of the intervention (TG) is better than the natural course of AP (WCG). Beyond this, a wait-list design does not control for general therapeutic factors such as attention or expectation of a future symptom improvement. The intervention should be further evaluated against active interventions (e.g., children's relaxation training or parental counseling). Second, the wait-list design did not allow a more extended controlled follow-up, and the long-term effect of the intervention is unknown. Third, our sample sizes were too small for analyses according to gender, age group, or Rome III diagnosis.

Further studies should consider comparing this intervention to an active control group. Dismantling the components of the treatment could additionally clear up which components are effective and which are not. Measurement should be supplemented by a condition-specific assessment of HRQoL, the assessment of cognitive variables such as the children's ability to cope with symptoms and by follow-up assessment of psychopathology. Ambulatory recording of psychophysiological variables (e.g., heart rate variability) before and after treatment could contribute to figure out potential mechanisms of action.

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The authors declare that they have no conflict of interest.

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